JUL 3 2002

510(k) Summary for Heartstream XL Defibrillator/Monitor

K021453

Date Summary Prepared

May 3, 2002

Submitter's Name and Address

Philips Medical Systems
Healthcare Solutions Group
3000 Minuteman Road
Andover, MA 01810-1099

Contact Person

Richard J. Petersen
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Cardiac Resuscitation Solutions Division
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Device Name

Proprietary Name:	Heartstream XL Defibrillator/Monitor
Common Name:	Defibrillator/Monitor
Classification Names:	Low-Energy Defibrillator

Predicate Devices

The legally marketed devices to which Philips Medical Systems claims equivalence for the Heartstream XL Defibrillator/Monitor are as follows:

- LIFEPAK 12 Defibrillator/Monitor, Medtronic Physio-Control Corp.
- Heartstream XL Defibrillator/Monitor, Philips Medical Systems

The design of the proposed Heartstream XL Defibrillator/Monitor is substantially equivalent in safety and performance to the devices listed above.

Device Description

The Heartstream XL Defibrillator/Monitor is a full-featured manual defibrillator, designed for use by clinicians trained in Advanced Cardiac Life Support (ACLS) procedures. Manual operation allows users to select biphasic waveform energy levels for external defibrillation, intra-thoracic defibrillation, delivery of synchronized shocks, and non-invasive external pacing.

Intended Use

The Heartstream XL Defibrillator/Monitor is a fully featured, defibrillator intended for use by qualified medical personnel, trained in either Advanced Cardiac Life Support or in the operation of the device, in a hospital environment.

Comparison of Technology Characteristics

The Heartstream XL's Biphasic Truncated Exponential waveform utilized for intra-thoracic defibrillation shocks, is similar to the BTE waveform used in the LIFEPAK 12.

Nonclinical Tests Used in Determination of Substantial Equivalence

The testing performed to show substantial equivalence to the Lifepak 12 included:

- Waveform analysis, comparing the performance of the Heartstream XL BTE waveform to the LifePak 12 BTE waveform at various energy and impedance levels typical of intra-thoracic applications.

- Animal test data, comparing the performance of the Heartstream XL BTE to the Likepak 12 BTE in domestic swine.

Conclusion from Testing

Based on the results of the testing described above, it is concluded that the Heartstream XL BTE waveform for intra-thoracic defibrillation applications does not raise any different questions regarding the safety or effectiveness as compared with the predicate devices. It is considered to be substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 3 2002

Philips Medical Systems
c/o Mr. Richard J. Peterson
3000 Minuteman Road
Andover, MA 01810

Re: K021453
Heartstream XL M4735A Defibrillator/Monitor
Regulation Number: 870.1025, 870.5300
Regulation Name: Automated External Defibrillator, DC-Defibrillator Low Energy (Including Paddles)
Regulatory Class: III (three)
Product Code: MKJ, LDD
Dated: May 3, 2002
Received: May 6, 2002

Dear Mr. Petersen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

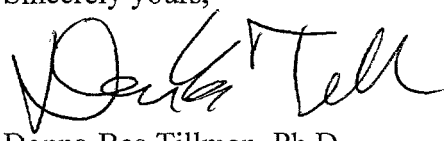
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Donna-Bea Tillman, Ph.D.
Acting Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): To be assigned K021453

Device Name: Philips Medical Systems, Heartstream XL Defibrillator/Monitor

Indications For Use: The Heartstream XL Defibrillator/Monitor is for use for the termination of ventricular tachycardia and ventricular fibrillation.

The device is for use by qualified medical personnel trained in the operation of the device and qualified by training in basic life support, advanced cardiac support, or defibrillation. It must be used by or on the order of a physician.

The SMART Biphasic waveform utilized in the Heartstream XL Defibrillator/Monitor has previously undergone clinical testing in adults. These trials support the waveform's effectiveness for defibrillation of ventricular tachyarrhythmias at 150J.

AED Therapy: To be used in the presence of a suspected cardiac arrest on patients of at least 8 years of age that are unresponsive, not breathing and pulseless.

Manual Defibrillation: Asynchronous defibrillation is the initial treatment for ventricular fibrillation and ventricular tachycardia in patients that are pulseless and unresponsive. The SMART Biphasic waveform utilized in the Heartstream XL Defibrillator/Monitor incorporates some user selectable lower energy levels that were not used in the clinical trials.

Synchronized defibrillation is indicated for termination of atrial fibrillation. The SMART Biphasic waveform utilized in the Heartstream XL has undergone clinical testing demonstrating its safety and effectiveness for cardioversion of atrial fibrillation.

There are currently no clinical studies related to the use of SMART Biphasic waveform in pediatric applications.

Pacing: Noninvasive pacing is one method of treating patients with symptomatic bradycardia. It can also be helpful in patients with asystole, if performed early.

SpO_2 Monitoring: SpO_2 monitoring is indicated for use when it is beneficial to assess a patient's oxygen saturation level.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular
and Respiratory Devices

510(k) Number K021453

Prescription Use ✓ or Over-The-Counter Use _____

(Per 21 CFR 801.109)